Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

13099

0 - FRONT

MEDWATCH
THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTARY reporting by health professionals of adverse events and product problems

Page 1 of 3 CFSAN

Form Approved OMB No 0910-0291 Expires 12/31/94
See OMB statement on reverse

FDA Use Only
Triage unit sequence # 89525
13099

A. Patient information

1. Patient identifier	2 Age at time of event: 20 or Date of birth:	3 Sex	4 Weight
[redacted] In confidence		☐ female ☒ male	____ lbs or ____ kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2 Outcomes attributed to adverse event (check all that apply)
- ☐ death ____ (mo/day/yr)
- ☐ life-threatening
- ☒ hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other: ____

3 Date of event (mo/day/yr): 7-2-98

4 Date of this report (mo/day/yr): 9-9-98

5 Describe event or problem

my Son was taking these Products from [redacted] & a few from the drug store. He speed his body up so much He lost weight & quite Sleeping. Had Headaches & became very TalKATive. was admitted to Hospital Soon diganose as Psychotic Schizphrenia was put on Strong Med. Took ___ day to get my son released Released as Psychotic Schizphrenia, on Strong meds. I did not give him meds & he returned to Normal Because of these things he was Misdiagnosed I'm very angry that we as Consumers

6 Relevant tests/laboratory data, including dates

are not made more aware that Thing Sold in [redacted] etc & Health food Stores Can be harmful if taken in large doses. I myself was diagnosed with migrane Headaches

7 Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

This disapear as these thing were stopped

"Son" – 13099
reporter/"myself" – 13125

C. Suspect medication(s)

1 Name (give labeled strength & mfr/labeler, if known)
#1 See list
#2

2 Dose, frequency & route used
#1 2 1/2 months
#2 2-3 times or more DAILY

3 Therapy dates (if unknown, give duration) from/to (or best estimate)
#1
#2

4 Diagnosis for use (indication)
#1 To Better Health
#2 & make Stronger

5 Event abated after use stopped or dose reduced
#1 ☐ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

6 Lot # (if known)
#1
#2

7 Exp. date (if known)
#1
#2

8 Event reappeared after reintroduction
#1 ☐ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

9 NDC # (for product problems only)
– –

10 Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1 Brand name

2 Type of device

3 Manufacturer name & address

4 Operator of device
- ☐ health professional
- ☐ lay user/patient
- ☐ other

RECEIVED SEP 23 1998

6. REC'D.
model #
catalog #
SEP 18 1998
serial #
lot # MEDWATCH CTU
other #

5 Expiration date (mo/day/yr)

7 If implanted, give date (mo/day/yr)

8 If explanted, give date (mo/day/yr)

9 Device available for evaluation? (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on ____ (mo/day/yr)

10 Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1 Name, address & phone #
[redacted]
000001

2 Health professional? ☐ yes ☒ no

3 Occupation: Data Entry Operator

4 Also reported to
- ☐ manufacturer
- ☐ user facility
- ☐ distributor

5 If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. ☒

Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

FDA Form 3500 (6/93) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CTU 89525

ADVICE ABOUT VOLUNTARY REPORTING

Report experiences with:

- medications (drugs or biologics)
- medical devices (including in-vitro diagnostics)
- special nutritional products (dietary supplements, medical foods, infant formulas)
- other products regulated by FDA

Report SERIOUS adverse events. An event is serious when the patient outcome is:

- death
- life-threatening (real risk of dying)
- hospitalization (initial or prolonged)
- disability (significant, persistent or permanent)
- congenital anomaly
- required intervention to prevent permanent

amage

n the product caused the

ll the details

blems – quality, performance
uch as:
nination
bility
ients
r labeling

How to report:

- just fill in the sections that apply to your report
- use section C for all products except medical devices
- attach additional blank pages if needed
- use a separate form for each patient
- report either to FDA or the manufacturer (or both)

Important numbers:

- 1-800-FDA-0178 to FAX report
- 1-800-FDA-7737 to report by modem
- 1-800-FDA-1088 for more information or to report quality problems
- 1-8[redacted] VAERS form
  accines

If your serious adverse event w occurred in a facilit side a dc y may be legally re to report nufacturer. Please the perso uld handle such re

Confidentiality: The patient's identity is held confidence by FDA and protected to the fullest ex the law. The reporter's identity may be shared wi manufacturer unless requested otherwise. Howe FDA will not disclose the reporter's identity in res a request from the public, pursuant to the Freedo Information Act.

The public reporting burden for this collection of information has been estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send your comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Reports Clearance Officer, PHS
Hubert H. Humphrey Building,
Room 721-B
200 Independence Avenue, S.W
Washington, DC 20201
ATTN: PRA

and to:
Office of Management and Budget
Paperwork Reduction Project
(0910-0230)
Washington, DC 20503

Please do NOT return this form to either of these addresses.

FDA Form 3500-back **Please Use Address Provided Below – Just Fold In Thirds, Tape and Mail**

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Rockville, MD 20857

Official Business
Penalty for Private Use $300

NO POSTAGE NECESSARY IF MAILED IN THE UNITED STATES OR APO/FPO

BUSINESS REPLY MAIL
FIRST CLASS MAIL PERMIT NO. 946 ROCKVILLE, MD

POSTAGE WILL BE PAID BY FOOD AND DRUG ADMINISTRATION

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MEDWATCH
The FDA Medical Products Reporting Program
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20852-9787

89525

1. DHEA:
dehydroepiandrosterone 50mg Vitamin C 15mg

2. Hydroxycut:
Hydroxagen 2000mg
(supplying 1000mg of hydroxycitric Acid)
MA Huang Extract 334mg
(standardized for 6% ephedra)
Guarana Extract 910mg
(standardized for 22% caffeine)
Willow Bark Extract 100mg
(standardized for 15% salicin)
L-Carnitine 100mg
Chromium Picolinate 300mg

3 Mini Two-way Action! Mini Thins
25mg Ephedrine HCL
200mg Guaifensenin

4 PRO RX
Vitamin A, C, D, E Thiamin, Riboflavin, Niacin
Vitamin B-6 Folic Acid, B-12
Biotin, Pantothenic Acid, Phosphrus,
Iodine, Magnesium, Zinc, Copper.
Potassium Sodium Protein,
Phenylalanine

5. AMINO Fuel. L-carnitine & Branched Chain
Amino Acids
Protein Amino Acids, 15g Carbohydrates, 10g
L-Alanine - 1200mg L-Arginine 1100, L Aspartic Acid - 1240mg
L-Carnitine - 25mg L-Cystine 919mg, Glycine 3200mg
L-Glutamic Acid 2040 mg, L-Histidine - 460mg
L-Isoleucine 230 L-Leucine 900, L-Lysine, L-methionie
Phenylalanine 400mg, Proline 2130,
L-Serine 540mg, L-Threonine 480mg
L-Tryptophan 82mg L Tyrasine 200mg L Valine

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89525 over

The eight essential Amino Acids
The L-tryptophan
B-1, B-2, B-3, B-6 - B-12
Pantothanic Acid, Folic Acid Biotin
PABA Choline Bitartrate
Inositol,

6 Diet System

Citrimax (Garcinia)	1500 mg
Kola Nut	550 mg
Guarena Extract	100 mg
Chromium Picolinate	300 mg
Choline Bitartrate	100 mg
Betaine HCL	25mg
L-Carnintine Complex	300mg

7 Golden Seal Roots

89525

CFSAN

September 9, 1998

My son had been taking several different drinks from [redacted] Some things were also purchased at the local drug store. He had gotten into the health program real heavy. Wanting to improve myself as well I also was on several of the health improvements. He was drinking some of these drinks 3-4 times a day sometimes more. Thinking that these thing were healthy because the has vitamins and other thing good for the body. As in fact they came from a health food store. More strength more energy and to look good is a plus. So all in all it would make sense that since these thing were good for you and healthy that they are harmless. How far from the truth can this be? Let me tell You. For myself I was diagnosed with migraine headaches. At this point in time I did not contribute it to these drinks and pills. They were good for you. My son keep on until he lost about 20 lbs and was sleeping 2-3 hours a night. Eventually he was not sleeping at all and a lose of appetite. After several day of no sleep no food and talking 90 miles a minute and his thought were getting confused. I took him to a doctor and explained what was going on. He in turn sent us to a hospital. My son ended up in a hospital for 30 day and was put on strong drugs which he had adverse reaction to. I spent 30 days trying to prove his sanity. He was diagnosed as Psychosis Schizophrenia which he is not never has been and hopefully never will be. To get him out of this place I had to promise to keep him on this medication & make an appointment with a Psychiatric doctor who could also prescribe medication. When I got him home I did not give him the medicine because I knew what had happened to him. He had speed his self up on these drinks. I realized also that they were the cause of my little episode. Being off the Halloo, Olanzapine, Verapasmil and cogentin. his doctor can find nothing wrong with him. The thing is if I had not known what had cause my sons reaction I would have kept him on the medication and he would be a nonproductive person today. He was suppose to stay on the medicine for the rest of his life. I feel that the general public needs to be made aware that just because you purchase something in a Health Food Store does not mean it is good for you. The idea of more is better and will make you healthier faster is also a misconcept. My Son and I learned the hard way. Please alert the general public as to what can and will happen with these things. My Son was misdiagnosed and could have been dysfunctional for the rest of his life. If I had not done reasearch on these things and took him off of his medication. I can not even begin to describe the pain, heartache, anxiety. We both lost 30 days of our lives.

From my personal experience mixing ephedrine with Amino Fuel and Diet Six. will make you have severe headaches. It feels as if there is a vise around your brain and it is squeezing it . It will make your eyeballs feel as if something is trying to push them out of your head. You will not be able to tolerate noise.

Something needs to be done to educate the general public about these things.

Thank You

[redacted]

Home: [redacted]
Business: [redacted]

REC'D.

SEP 1 8 1998

MEDWATCH CTU

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89525

Adverse Event Questionna

Complaint Number: 13099 **Investigator:** Gerald Miecle

Consumer Information

Date of Report: 03/04/99 MM/DD/YY

Initial Report Source: ☐ORA Consumer Injury
☐Telephone ☐Correspondence ☒MedWatch
☐USP ☐PQRS ☐Poison Control ☐CDC

Nam [redacted] Gender: ☐F ☒M Age: 21 [redacted]

Race: ☒1-White ☐2-Black ☐3-Asian/Pacific Islander ☐4-Native American ☐5-Hispanic
☐8-Other _____ ☐9-Unknown

Information on Adverse Event

Date of Adverse Event: ~~7/1/98~~ 7/2/98
Previous Adverse Effects to Product Type: ☒Yes ☐No 7/1/98

Give the site of consumption/ingestion (e.g. home, restaurant, office): Home

The following information relates to the consumers' use of the product.

Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms):
See Medical Records

How long did the symptoms last?
Give the circumstances of exposure (i.e. how much was taken, how was the product taken, how often was it taken, etc.). See Below

List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event:

Did event abate after use of suspected product stopped or dose reduced: ☐Yes ☐No ☐Unknown
Did symptoms reoccur after reintroduction of suspected product: ☐Yes ☐No ☐Unknown ☐Not Applicable
Did symptoms reoccur after using other products with the same ingredients: ☐Yes ☐No ☐Unknown ☐Not Applicable

Medical Information

Was a health care provider seen?: ☒Yes ☐No
Give health care provider's name, address and telephone number:

Occupation of Health Care Provider: ☒MD ☐Osteopath ☐Naturopath ☐Nurse ☐Pharmacist ☐Other (specify)

What medical tests were performed and what were the results?

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What was the medical diagnosis?
What treatment(s) was given (e.g., drugs, other)?

MedWatch #13099 Investigation
ATT # 3 Pg# 1 of 2
4-5 March 1999 GM

Were there any preexisting condition(s)/treatment(s)?
(If YES, list them including allergies, and chronic diseases): ☐Yes ☐No

Remarks: Started taking supplements early May 1998.
① EARLY May 25 mg Mini Two way Action w 2 cups Coffee & 300mg ASA @ BID/2 wks
② - 1 wk break "Mini Two-Way Action" Lot# 98F039G 6/00
③ - start back w ① / 1 mo
④ - Reduced to days when he lifted weights 5 or 6 days wk, Took once or twice day / 2 wks
⑤ - started Early May took as labeled "Hydroxycut 4 caps morning & afternoon / 45 days "Hydroxycut 80 caps 3692/M10-99"

Product Category

1. Adverse event attributed to:
   ☐**Medical Food** (under medical supervision) ☐**Infant Formula**
   ☒**Dietary Supplement** (a vitamin; an essential mineral; a protein; a herb or similar nutritional substances including botanicals such as ginseng and yohimbe; amino acids; extracts from animal glands; garlic extract; fish oils; oil of evening primrose; fibers such as psyllium and guar gum; compounds not generally recognized as food or nutrients, such as bioflavonoids, enzymes, germanium, nucleic acids, para-amino-benzoic acid, and rutin; and mixtures of these ingredients.)
   ☐**Other** (traditional food) _____

Other Product Problems

2. ☐Foreign Object
(specify):_____

3. ☐Other (specify):
_____

Information on Suspected/Alleged Product

Give the product name and manufacturer as listed on the label (including the recommended dosage/serving size, recommended duration of use, and indications for use as listed on the label):

See

List product ingredients (if ingredients are suspected to be present, but not verified, list as suspected):
☐Check here if ingredients are unknown

_____

_____

_____

If a particular ingredient is suspected of contributing to the adverse event, please indicate the appropriate category below:

☐Aspartame ☐Color Additive (please specify) _____
☐Monosodium Glutamate
☐Sulfite
☐Other Ephedrine "Ephedra"
☐Unknown

Is the product label available, if yes submit a quality copy along with this questionnaire: ☐Yes ☐No ☐Unknown
Product Sample Available: ☐Yes ☐No ☐Unknown

Outcome Attributed to Adverse Event:
(If yes, include pertinent medical records)

Death: ☐Yes ☒No

Life-Threatening: ☒Yes ☐No Potential Danger to self

Hospitalization: ☒Yes ☐No (if YES, indicate if initial or prolonged) 30 days

Required intervention to prevent permanent impairment/damage: ☒Yes ☐No

Did the adverse event result in a congenital anomaly: ☐Yes ☐No

MedWatch #13099 Investigation
ATT # 3 Pg# 2 of 2
4-5 March 1999 GM

FROM THE DE[illegible] OF
Gerald Mierle, Investigator
Food and Drug Administration
[redacted]

MEMORANDUM

Date: 8 March 1999

From: **Gerald Mierle**

Subj: MedWatch # 13099 Documents

To: Bridgette M. Wallace, ARMS Monitor, HFS-636

Attached are the Investigational Records of MedWatch # ~~13009~~ 13099 as requested. The investigation included WedWatch # 13125 also with its records sent under separate cover. The mother of the patient in MedWatch # ~~13009~~ 13099 submitted MedWatch # 13125 and # ~~13009~~ 13099.

All of the records for MedWatch #13099 were collected from the patient's Lawyer [redacted]. She is a partner with the firm of:

[redacted]

Ms. [redacted] has control of the medical records, Nutritional Supplements, and empty containers. She had interviewed the patient in MedWatch # 13099. When I contacted the mother she had referred me to the lawyer's office. Ms. [redacted] was informative and copied all of the pertinent medical records in this investigation for the FDA. She also copied the labeling of the "Hydroxycut" and the "Mini Two Way Action" Tablets, both of which contain ephedrine. She also gave 20 tablets of the "Mini Two Way Action" as a sample. Receipt for sample was issued for the sample and documents. Ms. [redacted] signed an "Authorization For Medical Records Disclosure" for the patient. The Sample is being held at the [redacted] under Lock and Key awaiting determination as to where it should be sent for analysis.

The sample was marketed by: BDI Pharmaceuticals, a division of Body Dynamics, INC A check of the national OEI lists the mfr type for Body Dynamics, Inc. as "D 53" & "L 60", CFN as 1831179, last EI date as 4/28/93 with Inspection conclusion as "A C" with reschedule date of "08/94" Priority "1".

ATTACHMENTS:

1. Assignment dtd November 10, 1998
2. Authorization For Medical Records Disclosure dtd 4 March 1999
3. Adverse Event Questionnaire dtd 4 March 1999

4. FDA 484 Receipt for Sa[redacted]e dtd 4 March 1999

5. OEI Print Screen for Body Dynamics, Inc.

EXHIBITS:

1.Unpurged Medical Records on patient identified in **MedWatch # 13099**

2. Labeling for "Hydroxycut" lot # 36921 10/99

3. Labeling for "Mini Two Way Action" lot # 98F0396 6/00

4. Confidentiality Statement for [redacted] **to Law Firm**

Gerald Mierle, CSO
[redacted]

Distribution:
ORIG: Wallace, HFS-636
CC: Kevin Morrow, BLT-DO, R&E
BLT-DO [redacted]
Wallace, HFS-636 (Additional Copy)

FROM THE DESK OF
Gerald Mierle, Investigator
Food and Drug Administration
[redacted]

MEMORANDUM

Corrected Copy

Date: 8 March 1999

From: Gerald Mierle

Subj: MedWatch # 13099 Documents

To: Bridgette M. Wallace, ARMS Monitor, HFS-636

Attached are the Investigational Records of MedWatch # 13099 as requested. The investigation included WedWatch # 13125 also with its records sent under separate cover. The mother of the patient in MedWatch # 13099 submitted MedWatch # 13125 and # 13099.

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Gerald Mierle, CSO
[redacted]

Distribution:
ORIG: Wallace, HFS-636
CC: Kevin Morrow, BLT-DO, R&E
BLT-DO, [redacted]
Wallace, HFS-636 (Additional Copy)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[redacted]

Telephone:
FAX: [redacted]

Date: 27 May 1999

To: Constance Hardy, CFSAN

Subject: Memorandums on MedWatch Numbers 13099 & 13125

From: Gerald Mierle, CSO

As per our conversation of 27 May 1999, the following items are addressed:

1. The missing memorandum for MedWatch 13125 has been sent by e-mail attachment thru Banyan.

2. The memorandum for MedWatch 13099 had errors listing the MedWatch number 13099 as 13009. The correct number is 13099. The corrected memorandum also is being sent as an attachment with the above mentioned Banyan message.

3. The labeling for Hydroxycut was included in the collection report # 27459. There was no physical sample of the medication (nutritional supplement) to be collected.

Gerald Mierle, CSO
[redacted]